DEC 2 3 2011

SECTION 5 - 510(K) SUMMARY

Date of Summary: September 23, 2011

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Official Contact: Cheryl Brown – QA / RA Manager

Proprietary Name:	MED-RX Extension Set with T-Connector
Common Name:	Intravascular Administration Set
Classification Name:	Intravascular Administration Set, 880.5440 Intravascular Administration Set.
Class:	Class II
Product Code:	FPA
Predicate Device:	Baxter Interlink T-Connector Extension Set (K060074)

Device Description

The MED-RX Extension Set with T-Connector is offered in two configurations, identical except for the tubing length. The proximal end of the MED-RX Extension Set with T-Connector features a T-Connector with an injection port and an integral rotating male luer lock. The distal end has a female luer lock fitting. The inner and outer diameter of both devices is consistent at 0.040" and 0.095" respectively, while the lengths available are either 4" or 38". Each of the luer fittings (distal female luer lock and proximal rotating male luer lock) are provided with protective caps. The MED-RX Extension Set with T-Connector is provided sterile and is single use.

Indications for Use

The MED-RX Extension Set with T-Connector is intended to be used for administration or withdrawal of fluids to or from a neonatal patient as directed by a physician.

Substantial Equivalence

The information provided in the premarket notification demonstrates that the proposed device is substantially equivalent to legally marketed devices. The proposed MED-RX Extension Set with T-Connector is substantially equivalent to the predicate Baxter Interlink T-Connector Extension Set (K060074). Both devices have the same intended use for intravascular administration or withdrawal of fluids to or from a neonatal patient as directed by a physician. Both devices are provided sterile and are single use.

A comparison of features and principles of operation between the proposed device and predicate device is provided in Table 1 below.

Table 1: Comparison between MED-RX Extension Set with T-Connector and Baxter Interlink T-Connector Extension Set (K060074)

ATTRIBUTE	PROPOSED DEVICE – MED-RX Extension Set with T-Connector	PREDICATE DEVICE – Baxter Interlink T-Connector Extension Set (K060074)
General Indications		
Indications for Use	For administration or withdrawal of fluids to or from a neonatal patient as directed by a physician	Same
Type of Placement	Intravascular	Same
Intended for single patient use	Yes	Yes
Prescription	Yes	Yes
Intended Population	Neonatal	Same
Intended Environment of Use	Hospital	Same
Non Pyrogenic	Yes	Yes
Physical Specifications		
Tubing outer diameter	0.095"	0.090"
Tubing inner diameter	0.040"	0.040"
Approximate length	4" or 38"	6"
Design Features		
Distal Configuration	Female luer lock fitting	Same
Proximal Configuration	T-Connector with injection site and rotating male luer lock	T-connector with injection site and male luer slip adaptor or rotating male luer lock adaptor
Clamp	Slide clamp	Same
Caps	Protective luer caps as necessary	Same
Compatibility	Compatible with standard luer fittings	Same
Material Composition		
Tubing	Polyvinyl Chloride	Same
Connectors	Medical grade plastic	Medical grade plastic
Packaging and Sterilization		
Sterile	Yes	Yes
Sterilization Method	Ethylene Oxide (EO)	Gamma Radiation
Packaging Configuration	Medical grade peelable paper/ poly pouch	Polypropylene pouch

Summary of Differences

There are no significant differences between the proposed MED-RX Extension Set with T-Connector and the predicate device Baxter Interlink T-Connector Extension Set (K060074). Similarities between the proposed device and the predicate devices include identical indications for use and duration of use. The MED-RX Extension Set with T-Connector and the Baxter Interlink T-Connector Extension Set are sterile, single use devices, packaged in peelable pouches.

The proposed MED-RX Extension Set with T-Connector is to be offered in two different lengths: 4" and 38", whereas the predicate device is only available in a 6" length. The additional lengths of extension sets to be offered for the proposed device can be considered to have no impact on safety or effectiveness as the additional length is merely intended to increase the amount of accessible tubing for use. The proposed device has a slightly larger tubing outer diameter than the predicate device but the dimensions are effectively equivalent. Both devices feature luer connectors with protective caps as required and slide clamps are placed on each set. The design features of both the proposed device and the predicate device can be also considered equivalent as the configuration of the devices are identical.

Therefore, any minor differences between the proposed device and the predicate have been evaluated to have no impact on safety or effectiveness of the MED-RX Extension Set with T-Connector. Therefore the proposed device can be considered substantially equivalent to legally market devices.

Non-Clinical Test Summary

Verification of functional performance of the MED-RX Extension Set with T-Connector has been performed as per ISO 8536-4: 2007. The MED-RX Extension Set with T-Connector has successfully completed all required performance testing following the applicable guidelines of ISO 8536-4: 2007 including tensile strength, resistance to leakage under pressure, resistance to liquid leakage, particulate contamination, and chemical requirements. The MED-RX Extension Set with T-Connector was also tested for natural rubber latex content. Please refer to Table 2.

Table 2: Non-Clinical Test Summary

Test	Standard	Results
Tensile Strength –Tubing/T-Connector	ISO 8536-4:2007	Pass
Tensile Strength – Tubing/Female Luer Lock	ISO 8536-4:2007	Pass
Leakage under Pressure	ISO 8536-4:2007	Pass
Liquid Leakage	ISO 8536-4:2007	Pass
Particulate Contamination	ISO 8536-4: 2007	Samples met contamination index limit.

Test	Standard	Results
Chemical Requirements	ISO 8536-4:2007 per Clause 5 & 7	Pass
Natural Rubber Latex Content	Modified Lowry Method	Device does not contain natural rubber latex

Summary of Sterilization

Each MED-RX Extension Set with T-Connector is individually packaged using a medical grade peelable synthetic polymer reinforced paper with a film backing, and sterilized using ethylene oxide. Please see Table 3 for a summary.

Table 3: Sterilization Summary

Test Description	Standard	Results
Method of Validation	ANSI/AMMI/ISO 11135-1: 2007	Validated to a Sterility Assurance Level of 1×10^{-6}
EO Sterilization Residuals	ISO 10993-7: 2008	Pass
Bacterial Endotoxins	ANSI/AAMI ST72: 2002	Pass

Summary of Biocompatibility Tests

Biocompatibility testing was successfully completed on sterile finished devices. The MED-RX Extension Set with T-Connector is classified as a prolonged duration, indirect blood path contacting device. A summary of the testing completed and the relevant standards are listed in Table 4.

Table 4: Biocompatibility Test Summary

Test Description	Standard	Results
ISO MEM Elution with L-929 Mouse Fibroblast Cells (Cytotoxicity)	ISO 10993-5: 2009	Product code 10-1053XLU is considered non-toxic.
ISO Guinea Pig Maximization Sensitization Test (Method of Biomaterial Extracts)	ISO 10993-10:2002	Product code 10-1053XLU did not elicit a sensitization response.
ISO Intracutaneous Reactivity Test	ISO 10993-10:2002	Product code 10-1053XLU would be considered a non-irritant.
ISO Acute Systemic Injection Test	ISO 10993-11: 2006	The findings indicate that the requirements of the ISO Acute Systemic Injection Test have been met.
ASTM Hemolysis Assay – Extract Method	ASTM F-756-00	Product code 10-1053XLU is considered non-hemolytic and passes the test.
Materials Mediated Rabbit Pyrogen Test	USP 32: 2009 <151>	Product code 10-1053XLU is determined to be non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 2 3 2011

Ms. Cheryl Brown
Quality Assurance / Regulatory Affairs Manager
Benlan Incorporated
2760 Brighton Road
Oakville, Ontario
CANADA L6H 5T4

Re: K112799
Trade/Device Name: MED-RX Extension Set with T-Connector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: September 23, 2011
Received: September 27, 2011

Dear Ms. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety /ReportaProblem /default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov /MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112799

Benlan™

MED-RX® Extension Set with T-Connector

SECTION 4 - INDICATIONS FOR USE

510(K) Number (If Known): Not Known.

Device Name: MED-RX Extension Set with T-Connector

Indications For Use:

The **MED-RX Extension Set with T-Connector** is intended to be used for administration or withdrawal of fluids to or from a neonatal patient as directed by a physician.

Prescription Use:	✓	AND/OR	Over-the-Counter Use	N/A
(Part 21 CFR 801 Subpart D)			(21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Richard Chapman Dec 21, 2011

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112799